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Rx News Bulletin

Bureau of Narcotics & Dangerous Drugs

Missouri Department of Health and Senior Services

health.mo.gov/safety/bndd/index.php

# Loss of Drugs—What Gets Reported?

**Loss of Drugs—What Gets Reported?**

Based upon recent telephone calls, the Bureau of Narcotics & Dangerous Drugs has reviewed the reporting of controlled substance losses by registrants. The bureau wants to clarify that the Missouri state regulation is different and more stringent than the federal DEA regulation. The state regulation detailing the requirements for reporting is 19 CSR 30-1.034(2)(B). In breaking down the elements of this state regulation, there are losses and thefts, and then there are insignificant events. Here is how each is to be handled:

### Drugs are lost, diverted, stolen or you do not know what happened to them:

These are cases where a BNDD loss report is required. The big issue here is whether the drugs were stolen or diverted, which is a criminal act; or if the drugs were lost and you do not know what happened to them. In either case of theft or unexplained loss, a report is required. The BNDD must be notified of the loss upon discovery and the written form is due into the bureau within seven days. If a registrant needs more time to conduct an internal investigation, the registrant may contact the bureau to request an extension.

### Insignificant losses:

These are legal events that happen from doing day-to-day normal business activity. The drugs were not lost or stolen. Documentation in your records should support the occurrence and the reconciliation of your inventory.

Examples would be:

- A container of liquid is spilled;
- A tablet is broken or crushed and cannot be dispensed;
- Some substance is used and not recoverable during compounding, such as syrup clinging to the inside of a beaker.

Registrants are to keep accurate records so that they can reconcile their drug counts. When these legal incidents occur, these events are to be documented and attached to the annual inventory that is filed away.

### To determine if a loss report is required, consider the following helpful hints:

- Do I know exactly where the drugs went? If you do not know, then they are lost and a report is required.
- Were the drugs stolen or diverted in manner that violates a law? If the drugs were stolen or diverted illegally, then a loss report is required.
- What if I know what happened to the drugs and no crime or loss occurred? This would be an insignificant event to document and staple to the annual inventory. This would be like a bottle of tablets being dropped on the floor and now determined not to be sterile for dispensing.
- Diversions must be reported. The drug may not have been lost or stolen, but an example of diversion is when a pharmacy technician makes up false prescription, pays for the drugs, but removes drugs from the pharmacy unlawfully. A diversionis any unlawful activity involving controlled substances by a registrant or their employee or agent.

### What if a pharmacy dispenses based upon a fraudulent prescription?

Pursuant to Section 195.060, RSMo, pharmacies are to dispense controlled substances in good faith based upon prescriptions that are legally authorized. If a pharmacy dispenses in good faith, and then later learns that a patient has falsified a prescription, the pharmacy is a victim of fraud. The pharmacy would not have to submit a loss report in this case because they were the victim of an outside agency or person not employed in their pharmacy.

However, if the fraudulent prescription scheme involved an employee within the pharmacy, then this would be reported because it is employee diversion. If a pharmacy employee is generating false prescriptions and assisting another in the diversion, then the pharmacy would report this because the diversion took place by a registrant's employee inside the pharmacy.

## Missouri BNDD Registration and Telehealth Locations

Pursuant to Section 334.108, RSMo, a prescription for controlled substances cannot be authorized based solely upon internet communication. There has to be a sufficient physical examination by an authorized practitioner, along with a chart that documents a medical history, an established diagnosis, underlying conditions, patient consent, authorization records and medication authorized.

Practitioners in Missouri should already have a Missouri controlled substances registration at their primary practice location where they spend the most time. The issue being raised is by practitioners who are not located in Missouri but want to provide telehealth services to patients located in Missouri.

The Drug Enforcement Administration (DEA) requires the practitioner to have a DEA registration in the practitioner's home state where they are communicating from, and then also have a medical license and registration in the state where the patient is located. This means these practitioners must first have a Missouri state drug registration with the Bureau of Narcotics & Dangerous Drugs.

The Missouri location should be at the practice location where the practitioner will be performing the majority of their telehealth services and also the same location of the Missouri patient's chart. The law requires a physical examination and patient chart; therefore, the BNDD would require the out-of-state practitioner to be registered at the location where the Missouri patient's chart can be inspected by the BNDD.

## Partial Dispensing of Schedule II Controlled Substances

The United States Congress recently passed the Comprehensive Addiction and Recovery Act (CARA). A part of this federal legislation would change the way that Schedule II controlled substance could be partially dispensed. At this time, the Missouri state regulation is stricter and more limiting. The Missouri Department of Health and Senior Services is determining if the state regulation should be modified to correspond to the new federal law.

## Check It Out

You can find educational documents on the BNDD website at http://health.mo.gov/safety/bndd/publications.php. Documents such as the "CDC Opiate Prescribing Guidelines" and also "Preventing Prescription Fraud" can be viewed.

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